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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,755	10/30/2001	Toshihiro Shimizu	2522 US2P	1478

23115 7590 03/21/2005

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,755	SHIMIZU ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7,9,11-19,21-24,29,31 and 50-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7,9,11-19,21-24,29,31 and 50-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/14/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Request for Continued Examination, Information Disclosure Statement, and Request for Extension of Time filed 12/14/04, Amendment and Declaration filed 10/15/04.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/14/04 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5, 7, 9, 11-19, 21-24, 29, 31 and 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundberg (US 6,132,770).

Lundberg teaches an effervescent tablet comprising mixture of enteric-coated pellets (beads, particles, granules) containing proton pump inhibitor (ppi) core (acid-labile active substance) (column 3, lines 59 through column 4, lines 1-19). The core

material is chosen from celluloses, sugar, non-pareils, or mixture thereof, having size of 0.1-4 mm (100-4000 μm) (column 8, lines 11-54). The ppi is mixed with filler, binder, lubricant, disintegrant, surfactant, other additives, and alkaline reacting agent (basic salt), including, calcium and magnesium salts (column 8, lines 55 through column 9, lines 1-5). The filler, binder, lubricant, disintegrant, surfactant, and other additives, including sodium lauryl sulfate, microcrystalline cellulose, mannitol, and hydroxypropyl cellulose are disclosed in column 22, lines 53-57). The pellets are coated with one or more enteric coating layers comprising methacrylic acid copolymers, and an over coating layer (column 10, lines 16 through column 11, lines 1-21). The coated pellets are then compressed to tablets having hardness of 51-100 N (which if converted into kg would fall within the claimed range), and disintegrating time is about 55 seconds (see examples).

Lundberg does not teach the content of hydroxypropoxyl group in the hydroxypropyl cellulose as claimed in claims 52 and 53. However, Lundberg teaches the use of hydroxypropyl cellulose within the claimed amount (examples 5, 6, 8, and 12) to obtain the same result, namely, an effervescent (disintegrable) tablet having the claimed hardness and disintegrating time. Accordingly, it would have been obvious to one of ordinary skill in the art to, by routine experimentation determine a suitable hydroxypropoxyl group of the hydroxypropyl cellulose to obtain the claimed invention, because the reference teaches the use of a similar compound to achieve the claimed tablet having the desired hardness and disintegration time.

It is noted that Lundberg does not expressly teach the claimed amounts of the ingredients of claims 14-16. However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 1-3, 5, 7, 9, 11-19, 21-24, 29, 31 and 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundberg (US 6,132,770), in view of Watanabe et al. (Biol. Pharm. Bull. Vol. 18, No. 9).

Lundberg is relied upon for the reason stated above. Lundberg is silent as to the teaching of the disintegration time in one minute or less.

Watanabe teaches a rapid disintegrate compressed tablet comprising crystalline cellulose and low-substituted hydroxypropyl cellulose (L-HPC) (see page 1308, materials and methods section). The tablet which is rapidly disintegrated and dissolved in the mouth within 30 second, and having a crushing strength of 8-18 kgf (see page 1308, and page 1309, results and discussion section). Thus, it would have been obvious for one of ordinary skill in the art to prepare the effervescent tablet of Lundberg using crystalline cellulose and L-HPC in view of the teaching of Watanabe to obtain the claimed invention, because the references teach the advantageous results in the use of similar disintegrating agents for the same purpose, such as, Lundberg teaches the effervescent tablet is especially suitable for patients with swallowing disorders and in

pediatrics (column 3, lines 53-55), and Watanabe teaches that it is necessary to develop a new type of tablet having the characteristics of rapid disintegration and dissolution in saliva suitable for elderly patients, and patients having difficulties or experience inconvenience in swallowing (see page 1308).

Response to Arguments

Applicant's arguments filed 12/14/04 have been fully considered but they are not persuasive.

Applicant argues that the effervescent tablet taught by Lundberg dissolve in a glass of water, not in a patient's mouth. Applicant further indicates that the Examiner does not appear to understand this fact, and has insisted that "the burden is shifted to applicant to provide a side-by-side data showing the effervescent tablet taught by Lundberg does not dissolve in a patient's mouth in less than 1 minute". In response to applicant's argument, first, the burden of prove is shifted because Lundberg teaches the use of similar ingredients for the same active ingredient in a similar composition, *e.g.*, an effervescent tablet containing acid-labile active substance. When the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Second, although Lundberg is silent as to the teaching that the tablet dissolves in a patient's mouth, there is nothing in Lundberg's disclosure that would stop or prohibit one to ingest the effervescent tablet taught by Lundberg orally. Furthermore, there is nothing in the disclosure of Lundberg indicates that the tablet would not dissolve in a patient's mouth. Nonetheless, Applicant

insists that the tablet taught by Lundberg would not dissolve in a patient's mouth. Accordingly, a side-by-side data has been suggested.

Applicant argues that to satisfy the Examiner, Applicant has provide a Declaration showing the calculated amount of CO_2 which would be evolved in the unlikely event that the tablets of Lundberg were ingested orally. The Declaration under 37 CFR 1.132 has been fully considered, but is insufficient to overcome the rejection based upon Lundberg because: 1) the Declaration does not show a side-by-side comparison establishing that the tablet taught by Lundberg would not dissolve in a patient's mouth in one minute or less as being claimed; and 2) the amount of CO_2 evolved in a patient's mouth is not what being claimed. The Declaration refers only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Pertinent Arts

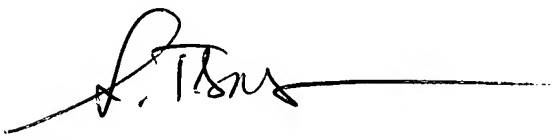
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ueda et al., Gergely et al., Misra et al., Mizumoto et al., Lattanzi et al., and Makino et al. are cited as of interest for the teachings of quick dissolving tablet.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Tran
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